

### **REMARKS**

This Amendment is being submitted in response to the Office Action dated November 13, 2008 in the above-identified application. Concurrently with this Amendment, Applicant submits a petition for a two-month extension of time for filing a response, along with the requisite fees and the authorization to charge our Deposit Account 50-0552 for any fee deficiencies. The time for filing a response to the November 13, 2008 Office Action is thereby extended to April 13, 2009.

The specification of the present invention has been amended. Specifically, Applicants respectfully submit that the title has been amended to be clearly indicative of the invention to which the claims are directed.

Claim 4 has been amended as suggested by the Examiner in the Office Action dated November 13, 2008. Claims 4 and 10 are pending in the case. Claims 1 to 3, 5 to 9 and 11 to 13 were previously canceled without prejudice. No new matter has been introduced by the amendments. Claims 4 and 10 are now pending and under examination.

In view of the amendments made herein and the remarks below, Applicants respectfully request reconsideration and withdrawal of the rejections and objections set forth in the November 13, 2008 Office Action.

### **SPECIFICATION**

In the Office Action, the Examiner objected to the title of the present invention as being "not descriptive." See Office Action, page 2.

The title of the present invention has been amended. Applicant respectfully submits that the amended title is clearly indicative of the invention to which the claims are directed. Withdrawal of the objection to the Specification is respectfully requested.

**REJECTIONS UNDER 35 USC §102**

Claims 4 and 10 were rejected under 35 U.S.C. 102(b) as being anticipated by Andersen et al. (US 2001/0020012 A1).

Claim 4 of the present invention recites: "A method of lowering the blood glucose level which comprises administering an effective dose of a growth hormone secretagogue receptor (GHS-R) antagonist to a patient with diabetes mellitus, wherein said GHS-R antagonist is selected from the group consisting of a ghrelin analog antagonist, [D-Lys-3]-GHRP-6 and [D-Arg-1, D-Phe-5, D-Trp-7, 9, Leu-11] substance P."

The Office Action admits that Andersen "is silent upon lowering blood glucose." See Office Action, page 5, line 2. The Office Action then asserts that "the administration of a GHS-R antagonist for the treatment of diabetes would inherently result in lowering blood glucose level as required by the claim 4." See Office Action, page 5, lines 2 to 4.

The Examiner states that "although the reference WO 01/87335 indicates that the administration of GHRP-2 does not change the plasma levels of insulin and glucose, this evidence does not affect the claimed invention, since GHRP-2 is a GHS-R agonist and not a GHS-R antagonist as recited in claim 4." See Office Action, page 4, fourth full paragraph.

The Applicant respectfully disagrees with the Examiner's position. The Applicant respectfully submits that Anderson merely confirms in Examples 3-5 that administration of the compounds (adenosine, NN703, NNC26-1187, NNC26-1291 and ghrelin) all of which are recognized to be GHS-R agonists stimulate feeding. Namely, the examples of Anderson show that GHS-R agonists stimulate feeding. According to the Examiner's above reasoning, it cannot be concluded that Anderson reference shows enabling disclosure that a GHS-R antagonist is effective in the treatment of diabetes mellitus.

The Office Action also states that “the reference by Andersen et al. still anticipates the claimed invention of this application by teaching a method for treatment of Type II diabetes (page 1, paragraph [0013]) with the antagonist for the receptor GHS-R 1A (page 2, paragraph [0022]), which a ghrelin analog antagonist.” Paragraph [0022] of Andersen recites: “In yet another embodiment of the invention the ligand is an agonist for the receptor GHS-R 1A. In another embodiment of the invention the ligand is an antagonist for the receptor GHS-R 1A.” See Andersen, paragraph [0022]. However, such a vague description in Andersen, which requires undue experimentation by one of skill in the art, is not appropriate as a basis for denying novelty under 35 U.S.C. § 102(b). See *Finisar Corp. v. DirecTC Group, Inc.*, 523 F.3d 1323, 1336 (Fed. Cir. 2008) (citing *In re Omeprazole Patent Litig.*, 483 F.3d 1364, 1379 (Fed. Cir. 2007)).

Applicants maintain that to establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by person of ordinary skill. As stated in *In re Oelrich*:

Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. See *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981)

Therefore, in order to conclude by the logic of inherency that GHS-R antagonist lowers blood glucose level based on the disclosure of Anderson, the Examiner is required to show that one of ordinary skill in the art who reads Anderson will recognize that GHS-R antagonist lowers blood glucose level. The Examiner has failed to meet this burden. The Office Action admits that Andersen “is silent upon lowering blood glucose.” See Office Action, page 5, line 2.

The Anderson does not show or teach “a method of lowering the blood glucose level which comprises administering an effective dose of a growth hormone secretagogue receptor (GHS-R) antagonist to a patient with diabetes mellitus, wherein said GHS-R

antagonist is selected from the group consisting of a ghrelin analog antagonist, [D-Lys-3]-GHRP-6 and [D-Arg-1, D-Phe-5, D-Trp-7, 9, Leu-11] substance P" as recited in claim 4 of the present invention.

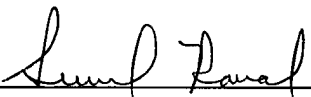
In view of the above, withdrawal of the rejection of independent claim 4 under 35 U.S.C. 102(b) is respectfully requested. As claim 10 is dependent on independent claim 4, withdrawal of the rejection of claim 10 under 35 U.S.C. 102(b), is also respectfully requested.

### **CONCLUSION**

In view of the amendments set forth herein and remarks above, Applicants respectfully submit that the pending claims are allowable, and solicit the issuance of a notice to such effect. If a telephone interview is deemed to be helpful to expedite the prosecution of the subject application, the Examiner is invited to contact Applicants' undersigned attorney at the telephone number provided.

Respectfully submitted,

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